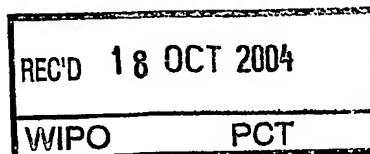


PCT/NZ2004/000231



CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 15 September 2003 with an application for Letters Patent number 528240 made by The Trustees of the Springfield Trust, namely Graham Francois Duirs and Lindsay Alison Duirs.

I further certify that the Provisional Specification has since been postdated to 23 September 2003 under Section 12(3) of the Patents Act 1953.

Dated 12 October 2004.

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH
RULE 17.1(a) OR (b)

Neville Harris
Commissioner of Patents, Trade Marks and Designs



POST-DATED UNDER SECT. 12(3)

TO 23-9-2003Intellectual Property
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15 SEP 2003

RECEIVED**PATENTS FORM NO. 4**Appln Fee: \$50.00
James & Wells Ref: 122508/28 MDL**PATENTS ACT 1953****PROVISIONAL SPECIFICATION****TREATMENT AND CONTROL DEVICE**

We The Trustees of the Springfield Trust, namely Graham Francois Duirs and Lindsay Alison Duirs, both New Zealand citizens of 17 MacFarlane Street, Hamilton, New Zealand do hereby declare this invention to be described in the following statement:

TREATMENT AND CONTROL DEVICE

TECHNICAL FIELD

This invention relates to a treatment and control device.

Reference throughout the specification now shall be made to use of the device in
5 relation to teats and mammary glands.

BACKGROUND ART

Infection in the udder is a major problem in dairy cows. It is caused by bacteria which in most cases enters the udder through the teat orifice.

It is the teat orifice or the streak canal that forms a primary defense mechanism
10 to invading micro-organisms. Deposits of keratin sit in the streak canal (sometimes known as the teat end canal) to form a natural defensive plug. Keratin contains high levels of naturally occurring antibacterial substances which inhibit the passage of bacteria. The keratin deposits are more dense in dry cows than lactating cows. The reason for this is that during the dry period, keratin
15 forms a solid shield which protects the teat from invading bacteria.

Sometimes dry period sub clinical mastitis can be carried on to manifest itself as clinical mastitis at calving or during the next lactation. *Streptococcus uberis* is a type of bacteria that commonly infects dry udders and appears as clinical mastitis at calving time.

20 Some types of treatments are administered at drying off to cure sub-clinical infections or as a preventative treatment designed to protect the udder from new infections during the high-risk dry period, especially immediately after drying off..

Dry period therapy often consists of antibiotics which are in a sustained release base to provide prolonged antibacterial protection during the period that the streak canal keratin is forming a natural seal or barrier against such infection risks.

- 5 Once the streak canal seal is in place, the risk of infections is lower. However, there is a tendency for new infections to occur during the immediate post-drying off period if cows are not treated with a protective dry period antibiotic.

Treatments for dry period therapy are often administered as infusions of antibiotics by a plastic needle or nozzle placed into the teat orifice and into the
10 streak canal or teat cistern (papillary sinus).

One example of this is US 4,472,374 which discloses an intramammary composition containing a siloxane elastomer incorporating an antibacterial agent.

In order to facilitate application to the teat, US 4,472,374 requires that "the elastomer must be of sufficiently low viscosity to facilitate the application to the
15 mammary glands by injection via the streak canal and teat cistern".

US 4,472,374 further teaches that the elastomer must remain sufficiently elastic to remain in place and soft enough to be milked-out at the onset of lactation. As such, an inert fluid silicone may be used to obtain "a liquid elastomer of the desired properties".

- 20 Best results were obtained in US 4,472,374 when the majority of the elastomer was infused into the teat sinus, and the remainder of the elastomer was discharged into the streak canal as the infusion means/applicator was withdrawn out of the teat.

US 4,472,374 however suffers from a number of disadvantages. In order for the low viscosity composition to be retained within the udder during the dry period, the majority of the compositions must be infused into the teat sinus, where the antibacterial agents are of little use in preventing mastitis and may also cause
5 additional problems such as irritations.

The low viscosity composition of US 4,472,374 also has no defined form, and thus does not permit any control to be exercised over the size or shape of the elastomer infused into the streak canal. Accordingly, it is not possible for a user to control the volume of elastomer infused into the streak canal and thus it is also
10 not possible to control the dose of antibacterial agent delivered.

Further, due to the low viscosity of the composition, it is difficult to ensure complete removal before lactation commences.

Lactating animals used for milk production are exposed to mechanical milking machines, normally twice a day. These machines apply vacuum pulsation to the
15 teat for milking purposes.

Understandably, mechanical milking can cause damage to the teat end. High vacuum, faulty pulsation and over-milking can bruise tissue and erode the teat end – breaking down the natural defenses of the teat. This can occur from infected teat lesions forming, damaged tissue and a loss of teat end integrity
20 allowing bacteria to enter the udder. These will also influence dry period new infections with the inability of the teat to form an effective keratin shield over the dry period.

In some situations, surgical procedures may be used to repair damaged teats. After surgery, an intramammary antibiotic is infused into the teat cistern to

prevent and/or treat mastitis, before a teat insert or sterile silicone implant is inserted into the teat canal to prevent the narrowing or collapse of the teat canal after surgery. However, these inserts are designed to provide temporary support for the teat canal only and do not themselves contain any medicament.

- 5 Mastitis occurs in various forms depending on the type of micro-organism causing the infection. It causes lost milk production, and adversely affects the flow and quality of milk. During lactation, mastitis can occur as clinical mastitis, which is visually recognising and treatable. Clinical mastitis is treated during lactation using a multiple number of antibiotic infusions at milking time. Care must be
10 taken to avoid contaminating the milk supply with antibiotic residues.

The economic significance of mastitis is considerable. The common way to treat mastitis is with intramammary antibiotics infused into the udder through the teat orifice and via the streak canal. The antibiotic is absorbed into the alveolus in secretory tissue where the infection normally resides. These antibiotics come in
15 various formulations but usually consist of an antibiotic formulated in paste or oil base which is infused by inserting a plastic tip through the orifice and squeezing the antibiotic from the tube into the udder.

The antibiotic is infused after milking. Since the cow must be milked regularly to maintain lactation and also to avoid discomfort, the cow is milked at the next
20 milking period, removing much of the antibiotic treatment. Consequently, repeated treatments are infused to maintain adequate drug levels. This milk must be discarded as it is contaminated with inhibitory substances.

Other problems associated with the present treatment of mastitis include:

- Treatment of cows at drying off as a preventative procedure requires an

antibiotic which can remain in the udder for 20 days over the cow's dry period. The antibiotic must have an active duration which does not contaminate the milk of fresh calved cows with antibiotic residues in the immediate post-calving period. In particular, antibacterial activity is important over the first ten
5 days of drying off.

- Treatment of clinical mastitis during lactation requires the infusion of one to three successive antibiotics into a lactating udder. Consequently, the cow must be milked each day with the treatment period being up to three days. Therefore when the antibiotic is infused, the main bulk of the antibiotic is
10 removed from the udder when the cow is milked at the next milking, requiring a further treatment after the milking to restore the required level of antibiotic to treat the infection.

The wastage of antibiotic in the removed milk and constant administration of a further treatment is costly. There is also potential risk from the farmer
15 inadvertently allowing the milk to go to the bulk tank. This can lead to the farmer incurring severe antibiotic residue penalties.

All references, including any patents or patent applications cited in this specification are hereby incorporated by reference. No admission is made that any reference constitutes prior art. The discussion of the references states what
20 their authors assert, and the applicants reserve the right to challenge the accuracy and pertinency of the cited documents. It will be clearly understood that, although a number of prior art publications are referred to herein, this reference does not constitute an admission that any of the documents form part of the common general knowledge in the art, in New Zealand or in any other
25 country.

It is acknowledged that the term 'comprise' may, under varying jurisdictions, be attributed with either an exclusive or an inclusive meaning. For the purpose of this specification, and unless otherwise noted, the term 'comprise' shall have an inclusive meaning – ie that it will be taken to mean an inclusion of not only the
5 listed components it directly references, but also other non-specified components or elements. This rationale will also be used when the term 'comprised' or 'comprising' is used in relation to one or more steps in a method or process.

It is an object of the present invention to address the foregoing problems or at least to provide the public with a useful choice.

10 Further aspects and advantages of the present invention will now be described by way of example only.

DISCLOSURE OF INVENTION

According to one aspect of the present invention there is provided a treatment or controlling device in the form of a shield capable of insertion into a teat orifice,
15 and

the shield also capable of being held in position in the teat once inserted therein characterised in that

the shield is configured to act as a substrate for natural keratin deposition.

According to another aspect of the present invention there is provided a treatment
20 or controlling device in the form of a shield substantially as described above characterised in that

the shield is configured so that it can deliver treatment substances to the streak canal.

One preferred configuration of the shield is configured so as to reside entirely within the streak canal, avoiding any external protrusions from the teat end with
5 sufficient space between the device and teat orifice such that keratin can fill the orifice and form a plug normally.

In preferred embodiments of the present invention the shield shall be used in relation to bovine teats. However, it is anticipated the present invention may find use in relation to a number of animal species used for milk production, having
10 high yielding mammary glands and a plurality of teats each consisting of teat cistern, streak canal and a single teat end orifice.

It should be understood that the term "streak canal" relates to the canal located between the papillary sinus and the teat end orifice. The streak canal is also known as the teat end canal and these terms may be used interchangeably.

15 The streak canal is thus distinguished from the teat cistern, which is also known as the papillary sinus or teat sinus.

The term "shield" should be taken to mean a device that is placed in the streak canal of the teat to prevent the unwanted passage of substances through the streak canal.

20 In preferred embodiments the shield will act to shield and protect the udder from infection that normally enters through the streak canal into the teat cistern and then invades the lactiferous sinus or udder due to failure of the teat's natural defences. However, this should not be seen as a limitation for the shield may

also act as a physical barrier to prevent milk leaking from damaged or abnormal teats, or to seal the teat following a form of therapeutic treatment. Additionally, the shield may act as a teat aperture control mechanism.

5 In preferred embodiments of the present invention the shield is made of a pliable, solid, preformed stable matrix which is able to deliver treatment substances, in specific quantities at the specific designated site. In contrast, the low viscosity pastes and gels previously used were not able to provide precise positioning of substance or control over the volume of composition infused, or thus the amount of antibacterial agent delivered.

10 Further, the low viscosity compositions were also difficult to remove following treatment, increasing the risk of residues contaminating the milk supply or blocking milk filters.

15 According to a further aspect of the present invention there is provided a method of treating an animal characterised by the step of inserting a shield substantially as described above in the animal's teat orifice.

According to a further aspect of the present invention there is provided an applicator which allows the shield to be inserted into the appropriate position in the streak canal without causing trauma or damage to the teat.

20 In preferred embodiments of the present invention, the delivery of the treatment substances is by a diffusion of those substances from the matrix that the shield is made from.

For example, the shield may be made of a silicone matrix which is impregnated with appropriate treatment and/or barrier substances. For example, these

substances may include antibiotics, antibacterial substances, tissue growth enhancers, vitamins and minerals, or may simply act as a plug to form a physical barrier.

5 Additionally, the treatment substances may be used to improve the healing of damaged teats.

The passage of harmful micro-organisms may thus be prevented by the sustained delivery of small, localised doses of such treatment substances in the streak canal and at the teat orifice – negating the requirement for high level infusions of traditional antibiotic compositions to prevent or treat infections.

10 The treatment substance may be delivered through dissolution processes from the teat shield matrix or by the placement of appropriate treatment substances within the inner core of the shield under various delivery systems.

In some preferred embodiments, the substance may be released by the biodegradation of the shield matrix over time.

15 A considerable advantage of the present invention is that its solid form allows the substances to be applied to the streak canal where they are needed, rather than into the teat cistern where substances are of little use or may cause additional problems such as irritation.

20 This localised, low volume application in the part of the teat exposed to the external environment ensures that bacteria can be killed at the point of entry, thus only a low amount of treatment substance is required, being not only good for the animal but also less expensive.

Further, as the treatment is not applied to the internal milk secretory glands, there

is less risk of contamination of the milk by treatment residues. In contrast, previous methods such as those disclosed by US 4,472,374 deliver high levels of treatment substances into the internal teat cistern and as such care is required to ensure all residues are removed to avoid contaminating the milk supply.

5 Preferably the shield is made of a soft non-irritant biomedical substance (although it can be made of other substances). Preferably the shield is sufficiently pliable so that the streak canal walls compress the shield in a similar manner that the walls normally compress keratin deposits. Thus, the streak canal walls can act in holding in the shield in a natural position within the streak canal.

10 Preferably the shield is of a dimension that can be readily inserted into the teat orifice with an acceptable degree of stretching of the streak canal wall.

Further, the shield is preferably designed to enable it to sit and be retained within the streak canal structure such that the teat end is able to close naturally and the surrounding smooth muscle layer can form naturally and without irritation around
15 the body of the shield, such that the shield is held firmly in place, avoiding loss of movement of the shield and be retained without interfering with normal keratin deposition.

In preferred embodiments of the present invention the shape and design of the shield are such that it will fit entirely within the streak canal such that there are no
20 protrusions into the teat cistern, being defined as penetrating inwards beyond the Furstenburg's rosette complex, or penetrating outwards beyond the external epithelium at the orifice of the teat end that may act as a vector for foreign material to enter the teat and cause infection.

The combination of the shield and the naturally occurring keratin aims to increase

the teat's natural defences against infection to a greater degree than keratin alone, particularly when teat ends may be damaged or eroded from milking machine trauma.

5 In preferred embodiments the shield is designed to dissolve anti-bacterial substances for a period equivalent to the period it takes normal keratin plugs to form, thereby providing early protection from infections before the natural defence system of the teat has been activated.

10 In some other embodiments there may be additional physical features on the shield, which can also enable its retention within the streak canal. For example, the shield may include a bulb or some other projection which does not irritate the teat tissues but provide sufficient resistance to removal from the teat during everyday activity by the cow. However, the shield must be such that the shield can be removed by the presence of milk build up as lactogenesis commences or be removed by a farmer or veterinarian.

15 It is envisaged that the bulb in addition to its role of locating the teat plug and preventing fall-out will also provide a cushion for the terminal end of an applicator if one is used to insert the shield.

20 The retaining device will now be referred to as a bulb, although this description should not be seen as limiting. It is envisaged that the bulb is connected to a shaft which fits within the streak canal. In some embodiments, the shaft may be of a length comparable to an average streak canal such that the bulb sits inside the teat cistern, in such a way as to not irritate or disturb tissue.

The shape and design of the shield is preferably such that it can withstand minimal milk pressures that occur at drying off without the shield being ejected

from the teat.

Immediately prior to calving, the udder of the cows become engorged at the onset of lactogenesis. The shield can then be ejected either naturally, from calf suckling or from hand stripping.

- 5 Alternatively, the shield may be composed of a suitable matrix that biodegrades over a given time period equivalent to the period it takes for normal keratin plugs to form, thereby allowing the shield to be ejected with the keratin plug at the onset of lactogenesis.

- 10 Preferably, the configuration and material construction of the present invention is that the pressure generated as a consequence of lactogenesis is sufficient to dislodge the shield from the streak canal. This is desirable so that once the cow has calved, the calf can immediately suckle on the teat unimpeded. This can understandably save the farmer a considerable amount of labour.

- 15 In the event that a shield should fall into the teat cistern the design is preferably such that the shield can be ejected by using the force of hand stripped milking as a means of removing the shield, or alternatively will biodegrade quickly.

- 20 The applicant in preferred embodiments of the present invention has designed the shield so that it can enhance the role of keratin as a primary defense. The applicant envisaged that a shield in accordance with preferred embodiments will act as a symbiotic interface with endogenous keratin such that the accumulative beneficial effect of both defense systems (that is the diffusion of external treatment substances and the keratin) are greater than the keratin alone.

The shaft may come in a variety of forms and in one embodiment may be

completely smooth so as to avoid irritating the streak canal. However, in preferred embodiments the shaft has a number of grooves along its length. There may of course be other recesses in the shield, for example a spiral thread.

5 In some embodiments there may also be a plurality of circular protrusions spaced along the length of the shaft. These protrusions can be tapered or rounded to allow easy insertion of the device while making it more difficult for the device to be dislodged during normal movement of the animal.

10 The grooves and circular protrusions may be manufactured in such a way to cause minimal dislodgment of keratin at insertion and to contain endogenous keratin as well as to sustain the synthesis of the keratin, so not to impair the teat's natural defenses.

15 The applicant believes that the provision of grooves and protrusions will accommodate the keratin produced by the teat which contains natural antibacterial substances enabling the symbiosis between the natural defense system and the provided defense system.

It should be appreciated that the nature of the teat shield itself in many respects acts as a physical equivalent of natural keratin such that both the physical barrier and inhibitory components of natural keratin are enhanced.

20 The shield also preferably acts as an immediate plug over the immediate post drying off period before natural keratin plugs have formed, to control any infections that may be resident in the end canal and prevent new mastitic infections over the post drying off period.

In some embodiments, the shaft may include a canal along it. This canal may act

as a reservoir and hold treatment substances. In other embodiments, the canal may allow the passage of instruments, other devices, substances or applicators.

In some embodiments the shield may be a teat cap. The teat cap may have a number of functions.

- 5 One function may be merely to prevent the shield penetrating too far into the teat, therefore the teat cap acts as a stop.

Another function is to act as a barrier to protect the teat end and streak canal and to enhance the animal's own primary teat defence mechanism against new infections entering the udder through the teat end.

- 10 In preferred embodiments the present invention will also act as a viable plug or shield in the streak canal in situations where the teat end has suffered damage or trauma from milking machines (teat end erosion) disease or injury, or situations where a naturally occurring effective keratin plug is unable to form, which previously rendered the teat susceptible to new infections.

- 15 The shield may also act as a plug to prevent the leakage of milk from the udder between milking and lactating cows naturally susceptible to this condition or from teat end damage.

In some embodiments of the present invention the cap may be completely solid and have no apertures therein.

- 20 In some embodiments of the present invention the teat cap may have an aperture. In these embodiments, the shield can be used as a delivery conduit for substances into the udder.

For example, it is desirable to deliver into the udder such compounds as antibiotics, hormones, low molecular weight biological substances such as oxytocin, prolactin and reproductive hormones.

Thus in the present invention, these substances may be injected into the aperture
5 so that they pass through the teat cap and along the shaft.

The injected treatment may pass out the distal end of the shield into the teat cistern.

In other embodiments the treatment may pass outwards through the walls of the shaft into the streak canal.

10 In other embodiments the device may act as an implant for the purposes of future delivery of substances to the lactiferous sinus, and may remain in position for an extended period of time.

In other embodiments, there may be provided an alternative delivery device which can utilise the present invention. For example, there may be provided a
15 mechanism which can be anchored to the streak canal shield for later retrieval after the treatment period.

Such a mechanism may be a collapsible slow release membrane balloon. The balloon can be inserted through the shield when in collapsed form. The balloon can then be injected or infused via the teat shield with treatment substances.
20 Once the substances have been delivered to the teat, the balloon can then be withdrawn in its collapsed form through the teat shield.

The balloon may deliver the substances through for example, dissolution and therefore will collapse naturally. In other embodiments, the balloon may be

punctured to collapse it before it is withdrawn through the streak canal shield.

To enable accurate placement of the collapsible balloon within the teat cistern, the shield may act as an anchor for the balloon component of the device.

5 It should be appreciated that the provision of an aperture in the teat shield may in some instances allow the cows to be milked while the shield is in position to control the teat orifice dilation and/or closure to control and/or improve milk harvesting.

10 For example, the shield may have a two-way valve system so that milk can be removed from the udder and the cow milked with the shield in place, yet still allowing substances to be inserted through an alternate valve as described above.

This may be achieved by the flexibility of the material used for the shield and the configuration of the valves (for example, flap valves) within the apertures.

15 A single aperture teat shield may also be milked to open and close as a normal teat being milked.

20 In other embodiments of the present invention there may be provided a controlled aperture or port within the teat shield. This may be mechanical or electronic. As discussed previously, considerable damage can be suffered by the teats during the milking process as a consequence of the vacuum pulsation used. This invention provides aperture control for the enhancement of milk harvesting.

For example, electronics within the teat shield may open or close the aperture as required by a milking machine.

Again, for example, instead of vacuum pulsation, there may be provided an inductive pulse which causes a solenoid or magnet to open and close the orifice as desired. Other methods of control are also envisaged.

BRIEF DESCRIPTION OF DRAWINGS

- 5 Further aspects of the present invention will become apparent from the following description which is given by way of example only and with reference to the accompanying drawings in which:

Figure 1 is a diagram showing the anatomy of a bovine teat, and

10 Figure 2 is a perspective view of two embodiments of the present invention, and

Figure 3 is a cross-sectional view of one embodiment illustrated in Figure 2, in position in a bovine teat.

BEST MODES FOR CARRYING OUT THE INVENTION

15 Figure 1 illustrates the anatomy of a bovine teat (1) so as to provide some clarification in terms of the placement of the present invention and its interaction with the anatomy of the teat (1). It should be noted that the streak canal (sometimes known as the teat end canal) (5) is at the entrance (12) to the teat. The teat cistern (papillary sinus) (3) is the volume that the streak canal (5) opens into.

20 With respect to Figures 2 and 3, there is illustrated a streak canal shield (7, 8) in accordance with two embodiments of the present invention.

The shield (7, 8) is made of a solid, pliable preformed matrix which can be easily

inserted and removed, but can be retained during the normal movement of the animal.

The shield (7, 8) has a pointed proximal end (14) to facilitate insertion, and a blunt distal end (15) to provide a location for an applicator for insertion.

- 5 The shield (7, 8) also includes a number of indented surfaces (13, 14) which act to capture and retain natural keratin (11) being produced by the streak canal (5). The keratin is a natural antibacterial substance which assists in improving the well-being of the teat (1).

- 10 The shape of the shield (7, 8) allows the surrounding smooth muscle layer (10) of the streak canal (5) to form naturally and without irritation around the body of the shield (7, 8), such that the shield (7, 8) is held firmly in place, avoiding loss of movement of the shield (7, 8) and be retained without interfering with normal keratin (11) deposition.

- 15 The length of the shield (7, 8) is configured such that the shield (7, 8) is located entirely within the streak canal, enabling the teat end to seal with keratin naturally (11).

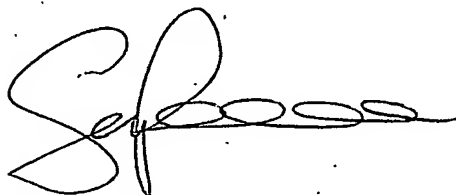
- 20 The shield (7, 8) is shaped so as to not have any sharp edges that could irritate the delicate tissues of the teat. The shield (7, 8) has sufficient width that it can be eased into the streak canal (5) and sit near the Furstenburg's Rossette (4) at the top of the streak canal (5). This helps to retain the shield (7, 8) within the streak canal (5).

Aspects of the present invention have been described by way of example only and it should be appreciated that modifications and additions may be made

thereto without departing from the scope of the present invention.

The Trustees of the Springfield Trust, namely
Graham Francois Duirs And Lindsay Alison Duirs

By their Attorneys

A handwritten signature in black ink, appearing to be 'S. Duirs', written over a horizontal line.

JAMES & WELLS

Intellectual Property
Office of NZ

15 SEP 2003

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FIGURE 1

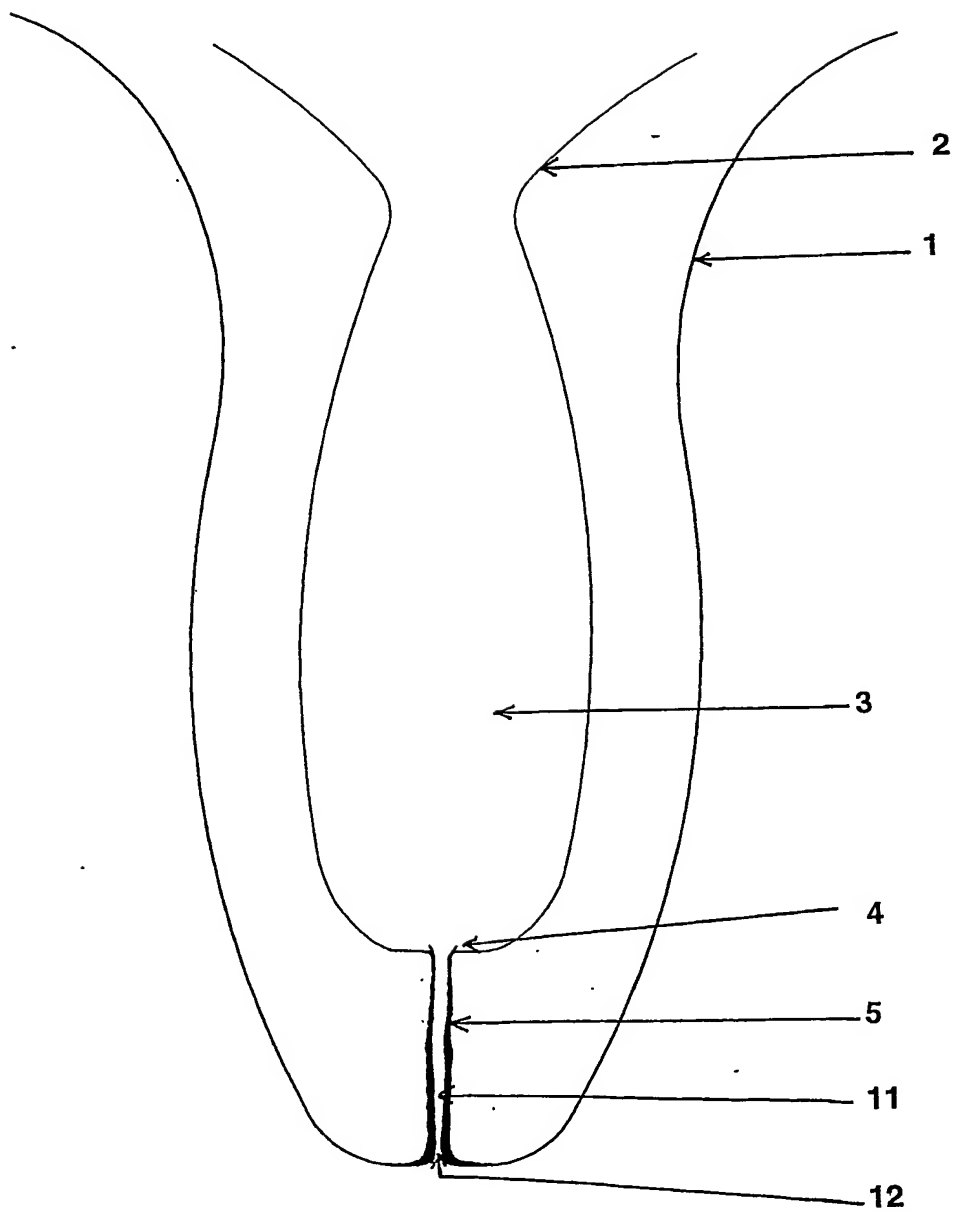


FIGURE 2

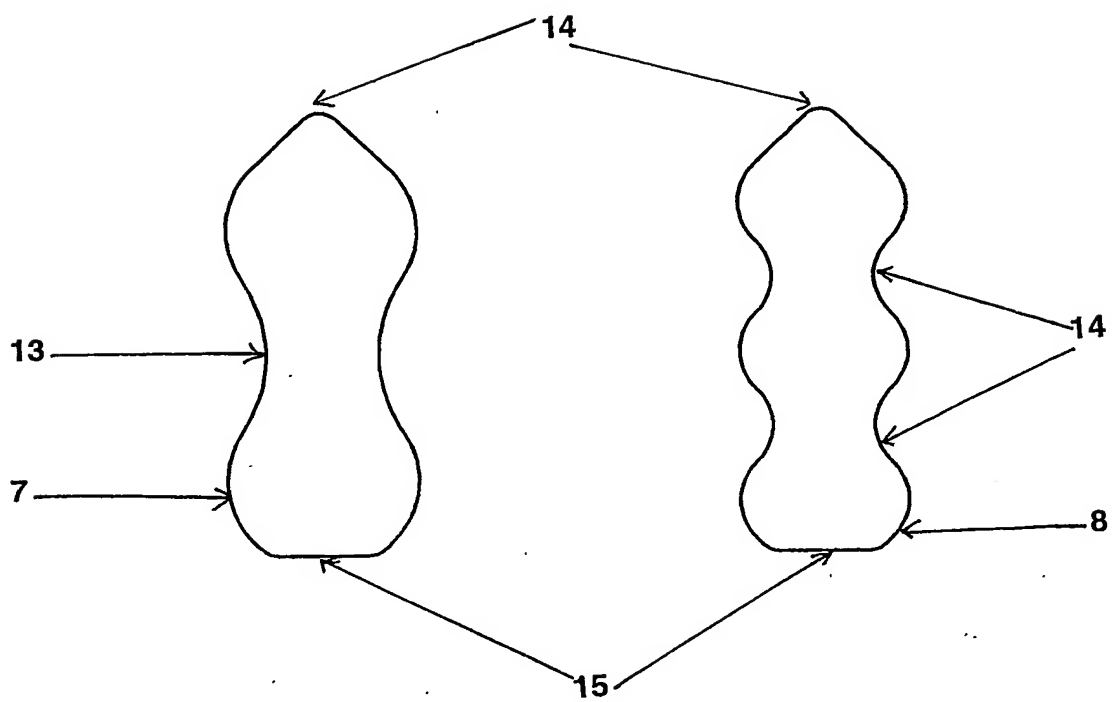


FIGURE 3